

10/734,640

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: October 18, 2004 (use as many sheets as necessary)				Complete if Known		
				Application Number	10/734,640	
Sheet		1	of	4	Filing Date	12/15/2003
					First Named Inventor	Bruno DE LIGNIERES
					Group Art Unit	1614
					Examiner Name	Not yet assigned
					Attorney Docket Number	029488-0111

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
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FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				

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In French	A2	J. BARRAT et al., "Effet <i>in vivo</i> de l'administration locale de progestérone sur l'activité mitotique des galactophores humains", J. Gynecol. Obstet. Biol. Reprod. 19: 269-274 1990.		
WR	A3	Bronaugh & Maibach, "Percutaneous Absorption Drugs-Cosmetics-Mechanisms-Methodology", Marcel Dekker Inc., New York, 1999.		
CR	A4	Philip CARTHEW et al., "Cumulative exposure to tamoxifen: DNA adducts and liver cancer in the rat", Arch Toxicol (2001) 75: 375-380.		
CR	A5	Gerard CHETRITTE et al., "Effect of Promegestone, Tamoxifen, 4-Hydroxytamoxifen and ICI 164,384 on the Oestrone Sulphatase Activity of Human Breast Cancer Cells", Anticancer Research 13: 931-934 (1993).		
CR	A6	Eric C. DIETZE et al., "Tamoxifen but Not 4-Hydroxytamoxifen Initiates Apoptosis in p53(-) Normal Human Mammary Epithelial Cells by Inducing Mitochondrial Depolarization", The Journal of Biological Chemistry Vol. 276, No. 7, Issue of February 16, 2001, pp. 5384-5394.		

Examiner Signature	<i>Chetritte</i>	Date Considered	2/23/07
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CR	A7	Ian S. FENTIMAN, "Tamoxifen and Mastalgia an Emerging Indication", Drugs, Vol. 32, No. 6, December 1986, pp. 477-480.	
CR	A8	I.S. FENTIMAN et al., "Dosage and duration of tamoxifen treatment for mastalgia: a controlled trial", BR. J. SURG. September 1988, Vol. 75, No. 9, pp. 845-846.	
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CR	A10	N. GIAMBIAGI et al., "IMMUNOLOGICAL DIFFERENCES BETWEEN THE ESTRADIOL-, TAMXIFEN- AND 4-HYDROXY-TAMOXIFEN-ESTROGEN RECEPTOR COMPLEXES DETECTED BY TWO MONOCLONAL ANTIBODIES", J. Steroid Biochem. Vol. 30, No. 1-6, pp. 213-217, 1988.	
CR	A11	IBIS investigators, "First results from the International Breast Cancer Intervention Study (IBIS-I): a randomised prevention trial", The Lancet, Vol. 360, September 14, 2002, pp. 817-824.	
CR	A12	V. Craig JORDAN et al., "Metabolites of tamoxifen in animals and man: identification, pharmacology, and significance", Breast Cancer Research and Treatment, 2, pp. 123-138.	
CR	A13	George G.J.M. KUIPER et al., "Comparison of the Ligand Binding Specificity and Transcript Tissue Distribution of Estrogen Receptors α and β ", Endocrinology, Vol. 138, No. 3, 1997, pp. 863-870.	
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CR	A15	Catherine MALET et al., "Tamoxifen and Hydroxytamoxifen Isomers versus Estradiol Effects on Normal Human Breast Cells in Culture", Cancer Research, Vol. 48, No. 24, December 15, 1988, pp. 7193-7199.	

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ll	A16	Pierre MAUVAIS-JARVIS et al., "trans-4-Hydroxytamoxifen Concentration and Metabolism after Local Percutaneous Administration to Human Breast", Cancer Research, Vol. 46, March 1986, pp. 1521-1525.	
ll	A17	Henri PUJOL et al., "Phase I Study of percutaneous 4-hydroxy-tamoxifen with analyses of 4-hydroxy-tamoxifen concentrations in breast cancer and normal breast tissue", Cancer Chemother. Pharmacol., 36:493-498 (1995).	
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ll	A19	David W. ROBERTSON et al., "TAMOXIFEN ANTIESTROGENS, A COMPARISON OF THE ACTIVITY, PHARMACOKINETICS, AND METABOLIC ACTIVATION OF THE CIS AND TRANS ISOMERS OF TAMOXIFEN" Journal of Steroid Biochemistry, Vol. 16, pp. 1-13, (1982).	
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ll	A22	Deborah N. ADER PhD, et al., "Prevalence and impact of cyclic mastalgia in a United States clinic-based sample", Am. J. Obstet. Gynecol., Vol. 177, No. 1, pp. 126-132, July 1997.	
ll	A23	M.R. CALLANTINE PhD. et al., "Micronized 17 β -Estradiol for Oral Estrogen Therapy in Menopausal Women", Obstetrics & Gynecology Vol. 46, No. 1, July 1975, pp. 37-41.	
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		Filing Date	12/15/2003
		First Named Inventor	Bruno DE LIGNIERES
		Group Art Unit	1614
		Examiner Name	Not yet assigned
Sheet	4	of	4
		Attorney Docket Number	029488-0111

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le	A26	R.E. MANSEL et al., "A Double Blind Trial of the Prolactin Inhibitor Bromocriptine in Painful Benign Breast Disease", Br. J. Surg. Vol. 65, (1978), pp. 724-727.	
le	A27	Catherine S. MURPHY et al., "Structure-Function Relationships of Hydroxylated Metabolites of Tamoxifen that Control the Proliferation of Estrogen-Responsive T47D Breast Cancer Cells In Vitro", Molecular Pharmacology, 38, pp. 737-743, (1990).	
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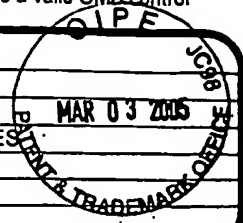
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: March 3, 2005 <i>(use as many sheets as necessary)</i>				Application Number	10/734,640
				Filing Date	12/15/2003
				First Named Inventor	Bruno DE LIGNIERES
				Group Art Unit	1614
				Examiner Name	Unassigned
Sheet	1	of	1	Attorney Docket Number	029488-0111



U.S. PATENT DOCUMENTS						
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		B1	DE 38 36 862 A1		Gunther Clemens et al.	5/3/1990		

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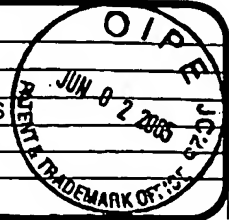
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT			Application Number	10/734,640
Date Submitted: June 2, 2005			Filing Date	12/15/2003
(use as many sheets as necessary)			First Named Inventor	Bruno DE LIGNIERES
			Group Art Unit	1614
			Examiner Name	Unassigned
			Attorney Docket Number	029488-0111
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WR	C1	4 919 937		Mauvais-Jarvis et al.	4/24/1990	
WR	C2	2003/0153543 A1		Masato TANABE et al.	8/14/2003	
WR	C3	5 189 212		University of Georgia Research Foundation	2/23/1993	

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WR	C4		EP 0 792 640 A2		PFIZER INC.	9/3/1997	
WR	C5		EP 1 106 179 A2		PFIZER INC.	6/13/2001	
WR	C6		WO 02/36129 A2		Alfred SCHMIDT et al.	5/10/2002	
WR	C7		WO 02/03969 A2		HEXAL AG	1/17/2002	
WR	C8		EP 1 177 787 A2		Pfizer Products Inc.	2/6/2002	

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WR	C9	International Search Report of PCT/EP03/15028		
—	C10	P. MAUVAIS-JARVIS, "Le traitement hormonal des mastopathies bénignes", Bull Cancer (1991) 78, 365-371.		
WR	C11	I.S. FENTIMAN et al., "Dosage and duration of tamoxifen treatment for mastalgia: a controlled trial", Br. J. Surg. 1988, Vol. 75, September, 845-846.		
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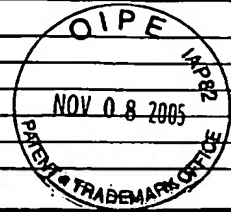
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DL	D1	2002/0115676 A1		David B. MACLEAN	8/22/2002	
	D2	2003/0065017 A1		PFIZER INC.	4/3/2003	
	D3	2003/0087885 A1		Valerie MASINI-ETEVE et al.	5/8/2003	
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DL	D6	Lawrence N. PARKER et al., "Treatment of Gynecomastia with Tamoxifen: A Double Blind Crossover Study", Metabolism, Vol. 35, No. 8, 1986: pp. 705-708.	

Examiner Signature	<i>Christy A. Lee</i>	Date Considered	2/23/2007
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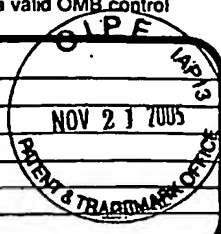
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		Number	Kind Code ² (if known)			

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lf	E1	BRISSON, J., et al., "Tamoxifen and Mammographic Breast Densities, Cancer Epidemiology, Biomarkers & Prevention, Vol. 9, pp. 911-915 (2000).		
lf	E2	"High Breast Density a Risk Factor", pp. 1-4, http://www.breastcancer.org/research_genetics_091902_pf.html (8/11/05)		

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: February 13, 2006 (Use as many sheets as necessary)		Complete if Known Application Number: 10/734,640 Filing Date: 12/15/2003 First Named Inventor: Bruno DE LIGNIERES Group Art Unit: 1617 Examiner Name: Jennifer M. Kim Attorney Docket Number: 029488-0111	
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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	F1	WO	2004/054557 A2		LABORATOIRES BESINS INTERNATIONAL	7/1/2004		
	F2	WO	2004/054558 A2		LABORATOIRES BESINS INTERNATIONAL	7/1/2004		

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Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
Date Submitted: August 28, 2006		Filing Date		12/15/2003	
(use as many sheets as necessary)		First Named Inventor		Bruno DE LIGNIERES	
		Group Art Unit		1617	
		Examiner Name		Jennifer M. Kim	
		Attorney Docket Number		029488-0111	
Sheet	1	of	1		

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<i>JK</i>	G1	2004/0138314	A1	BUA	7/15/2004	

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
<i>W</i>	G2	EP	1 579 857	A1	LABORATOIRES BESINS INTERNATIONAL	9/28/2005		
<i>W</i>	G3	EP	1 579 856	A1	LABORATOIRES BESINS INTERNATIONAL	9/28/2005		

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Examiner Signature	<i>Christine Lee</i>	Date Considered	2/23/2007
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